

(1) a flexible sewing cuff,  
(2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and  
(3) means for securely attaching said prosthesis valve to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient;  
and

B) a tool for attaching said flexible sewing cuff to the patient in a minimally invasive manner and which includes

(1) a housing,  
(2) an operating handle mounted on one end of said housing,  
(3) at least one fastener stored in said housing, said fastener having an elastic limit,  
(4) means for releasably mounting said flexible sewing cuff to said tool, and

(5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

3. (Twice Amended) In combination:

A) a multipart prosthesis which includes

- (1) a flexible sewing cuff,
- (2) a prosthesis valve separate from said flexible sewing cuff,

and

(3) means for attaching said prosthesis valve to said flexible sewing cuff after said flexible sewing cuff has been placed in a patient; and

B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes

- (1) a housing,
- (2) an operating handle mounted on said housing,
- (3) at least one fastener stored in said housing, said fastener

having an elastic limit,

(4) means for releasably mounting said flexible sewing cuff to said tool, and

(5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

14. (Amended) In combination:

A) a heart valve prosthesis which includes

- (1) a flexible sewing cuff,
- (2) a prosthesis valve separate from said flexible sewing cuff,

and

(3) means for securely attaching said valve to said flexible sewing cuff after said flexible swing cuff has been placed in a patient; and

B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes

- D<sup>3</sup>
- (1) a housing,
  - (2) an operating handle mounted on said housing,
  - (3) at least one fastener stored in said housing, said fastener

having an elastic limit, and

(4) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

15. (Amended) In combination:

A) a heart valve prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate and spaceable from said

flexible sewing cuff, and

(3) means for securely attaching said valve to said flexible

sewing cuff after said flexible swing cuff has been placed in a patient; and

B) a tool for placing said flexible sewing cuff in the patient in a

minimally invasive manner and which includes

(1) a housing,

(2) an operating handle mounted on said housing,

(3) at least one fastener stored in said housing, said fastener

having an elastic limit, and

(4) a fastener handling means on said housing and

operationally connected to said operating handle to be controlled by said operating

handle for storing said fastener and securing said fastener through said flexible

sewing cuff and into the patient's tissue to attach said flexible sewing cuff to the

patient without deforming said fastener beyond its elastic limit.

---

20. (Thrice Amended) In combination:

A) a multipart heart valve prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis heart valve separate and spaceable from said flexible sewing cuff, and

(3) anchor elements for securely attaching said prosthesis heart valve to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient;

B) a fastener for attaching said sewing cuff to the patient from one side of said sewing cuff, said fastener having an elastic limit and an initial shape;

and

C) means for forcing said fastener through said sewing cuff and attaching said sewing cuff to the patient without exceeding the elastic limit of said fastener.

Please add new claims 21-27 as follows:

21. In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate and spaceable from said

flexible sewing cuff, said prosthesis valve being attachable to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient, and

B) a tool operative to attach said flexible sewing cuff to the patient in a minimally invasive manner, the tool including

(1) a housing,

(2) an operating member mounted on one end of said housing,

(3) at least one fastener carried by said housing, said fastener having an elastic limit,

(4) mounting structure on said tool operative to releasably carry said flexible sewing cuff, and

(5) a fastener carrier on said housing, said fastener carrier being operatively connected to said operating member such that actuation of said operating member secures said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

D5  
Conf 22.

In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate from said flexible sewing cuff

and attachable to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient, and

B) a tool operative to attach said flexible sewing cuff in the patient in a minimally invasive manner, the tool including

(1) a housing,

(2) an operating member mounted on said housing,  
(3) at least one fastener stored in said housing, said fastener having an elastic limit,  
(4) mounting structure on said tool operative to releasably carry said flexible sewing cuff, and  
(5) a fastener carrier on said housing, said fastener carrier being operatively connected to said operating member such that actuation of said operating member secures said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

DS  
Conf 23.

In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,  
(2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and  
(3) anchor elements configured to attach said prosthesis valve to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and

B) a tool operative to attach said flexible sewing cuff to the patient, said tool including

- (1) a housing,
- (2) at least one fastener carried by said housing, said fastener having a tissue-penetrating shape and an elastic limit, and
- (3) a fastener handling device on said tool operating to force said fastener into the patient from one side of said flexible sewing cuff and the patient's tissue to attach said flexible sewing cuff to the patient and thereby deform said fastener beyond its elastic limit into a cuff-retaining shape.

24. In combination:

A) a multipart prosthesis which includes

- (1) a flexible sewing cuff,
- (2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and
- (3) anchor elements configured to attach said prosthesis valve to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and

B) a tool operative to attach said flexible sewing cuff to the patient, said tool including

- (1) a housing,
- (2) at least one fastener carried by said housing, said fastener being self-tapping to penetrate the patient's tissue when rotated,



(3) a fastener handling device on said tool operative to impart rotation to said fastener and thereby force said fastener into the patient's tissue from one side of the patient's tissue to attach said flexible sewing cuff to the patient.

25. In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate and spaceable from said

flexible sewing cuff, and

(3) anchor elements configured to attach said prosthesis

valve to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and

B) a tool operative to attach said flexible sewing cuff to the

patient, said tool including

(1) a housing,

(2) at least one fastener carried by said housing, and

(3) a fastener handling device on said tool operative to force

said fastener into the patient from one side of the patient's tissue and thereby

attach said flexible sewing cuff to the patient.

109

D

26. In combination:

A) a multipart prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis valve separate and spaceable from said

flexible sewing cuff, and

(3) anchor elements configured to attach said prosthesis

valve to said flexible sewing cuff after said flexible sewing cuff has been attached

to a patient;

B) a fastener for attaching said sewing cuff to the patient from one

side of said sewing cuff, said fastener having an elastic limit; and

C) a tool operative to force said fastener through said sewing cuff

and thereby attach said sewing cuff to the patient without exceeding the elastic

limit of said fastener, whereby said fastener is nonformed when said sewing cuff is

attached to the patient by said fastener.

27. In combination:

A) a multipart heart valve prosthesis which includes

(1) a flexible sewing cuff,

(2) a prosthesis heart valve separate and spaceable from said

flexible sewing cuff, and

110

D